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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/526,028	02/28/2005	Zhihui Liu	186326/US	4794
52835 7590 12/04/2007 HAMRE, SCHUMANN, MUELLER & LARSON, P.C. P.O. BOX 2902 MINNEAPOLIS, MN 55402-0902			EXAMINER KOSAR, ANDREW D	
			ART UNIT 1654	PAPER NUMBER
			MAIL DATE 12/04/2007	DELIVERY MODE PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

DETAILED ACTION

Election/Restrictions

This application contains claims directed to more than one species of the generic invention. These species are deemed to lack unity of invention because they are not so linked as to form a single general inventive concept under PCT Rule 13.1.

Claims 1-10 are generic to the OGP/G-CSF pharmaceutical compositions, where the OGP is human OGP or OGP-related peptides, including the human OGP of claim 6 (SEQ ID NO:1- please note the claim must be amended to reflect the sequence is SEQ ID NO:1) or the OGP-related peptides of claim 7.

Applicant is required, in reply to this action, to elect a single species to which the claims shall be restricted if no generic claim is finally held to be allowable. The reply must also identify the claims readable on the elected species, including any claims subsequently added. An argument that a claim is allowable or that all claims are generic is considered non-responsive unless accompanied by an election. A single species is one where a single OGP is identified in the composition with G-CSF, in addition to any additional elements which are present in the composition, e.g. the components of claim 3.

Upon the allowance of a generic claim, applicant will be entitled to consideration of claims to additional species which are written in dependent form or otherwise include all the limitations of an allowed generic claim as provided by 37 CFR 1.141. If claims are added after the election, applicant must indicate which are readable upon the elected species. MPEP § 809.02(a).

The species listed above do not relate to a single general inventive concept under PCT Rule 13.1 because, under PCT Rule 13.2, the species lack the same or corresponding special technical features for the following reasons:

Annex B, Part I(f) of the Administrative Instructions under PCT states that, "wherein a single claim defines alternatives (chemical or non-chemical)...the requirement of a technical interrelationship and the same or corresponding special technical features as defined in Rule 13.2, shall be considered to be met when the alternatives are of a similar nature."

The alternatives must comply with subsections (i)(A) and one of either (i)(B)(1) or (i)(B)(2), which requires that, "all alternatives have a common property or activity" and "a common structure is present, i.e., a significant structural element is shared by all of the alternatives" (B)(1) or "in cases where the common structure cannot be the unifying criteria, all alternatives belong to a recognized class of chemical compounds in the art to which the invention pertains." (B)(2).

In the instant case, the OGP peptides are asserted have the same activity/function (ostogenic/hematogenic activity), satisfying requirement (A). However, the claim fails to satisfy either (B)(1) or (B)(2). The claim recites no structure, thus failing to meet the requirements of (B)(1), particularly when OGP of claim 1 embraces OGP-related peptides $X_1X_2Y_1X_3FX_4X_5X_6X_7$, where X_2 and X_6 are absent, 1 or "several amino acids or a peptide" and $X_{3,4}$ and 5 are any amino acid, X_7 is carboxyl, amino or hydroxyl, X_1 is amino, acetyl, an acetylated amino acid or a deaminated amino acid and the amino acids of X_{1-6} are selected from the 20 natural amino acids. Thus, there is no significant structural element beyond the compounds being peptides and having amide bonds which does not rise to the level unity.

Further, in looking to subsection (f)(iii), it is stated that 'recognized class of chemical compounds' means that, "there is an expectation from the knowledge in the art that members of the class will behave in the same way in the context of the claimed invention. In other words, each member could be substituted one for the other, with the expectation that the same intended result would be achieved." One of skill in the art would not recognize these divergent compounds, or other compounds asserted to have said activity/function, as required, to function in the context of the instantly claimed invention. Thus, the claim fails to meet the requirement of (B)(2).

Applicant is advised that the reply to this requirement to be complete must include (i) an election of a species or invention to be examined even though the requirement be traversed (37 CFR 1.143) and (ii) identification of the claims encompassing the elected invention.

The election of an invention or species may be made with or without traverse. To reserve a right to petition, the election must be made with traverse. If the reply does not distinctly and specifically point out supposed errors in the restriction requirement, the election shall be treated as an election without traverse.

Should applicant traverse on the ground that the inventions or species are not patentably distinct, applicant should submit evidence or identify such evidence now of record showing the inventions or species to be obvious variants or clearly admit on the record that this is the case. In either instance, if the examiner finds one of the inventions unpatentable over the prior art, the evidence or admission may be used in a rejection under 35 U.S.C. 103(a) of the other invention.

Applicant is reminded that upon the cancellation of claims to a non-elected invention, the inventorship must be amended in compliance with 37 CFR 1.48(b) if one or more of the

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currently named inventors is no longer an inventor of at least one claim remaining in the application. Any amendment of inventorship must be accompanied by a request under 37 CFR 1.48(b) and by the fee required under 37 CFR 1.17(i).

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Andrew D. Kosar whose telephone number is (571)272-0913. The examiner can normally be reached on Monday - Friday 08:00 - 16:30.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Cecilia J. Tsang can be reached on (571)272-0562. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.


Andrew D Kosar
Patent Examiner
Art Unit 1654